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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
RYCKMAN, MELISSA K				
ART UNIT		PAPER NUMBER		
3773				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

khansen@imds.net

Office Action Summary

Application No.

10/648,068

Applicant(s)

FALLIN ET AL.

Examiner

MELISSA RYCKMAN

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 11-14, 16-23, 25-34, 36-42, 44, 45 is/are rejected.
- 7) ☒ Claim(s) 6, 15, 24 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to claims filed 9/22/09. The examiner spoke with Barbara Daniels on 3/24/10 regarding the rejection of claims 31 and 26. This office action clarifies/reconsiders the previous rejection as stated below.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the distal terminus of the second dilator being distal of the distal terminus of the first dilator (as described in claims 15 and 24) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 24 claims "when the first dilator is received *with* the passageway of the second dilator." The examiner believes "with" should be changed to "within."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5,8,11,16,19-23,31-33,37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Polleau (U.S. Patent No. 2,476,216).

Claims 1,11,22,23,31: Polleau teaches a dilation system for dilating bodily tissue (capable of being used as described), the dilation system comprising: an elongate first dilator (2") comprising a tubular body having an exterior surface extending between a proximal end and an opposing distal insertion end, the body also having an interior surface bounding a passageway extending between the proximal end and the distal insertion end (Fig. 5, 2" has inner surface); a first

mating member/inward tang (3", Fig. 4) formed on the exterior surface of the first dilator at the distal insertion end and an elongate second dilator (2') comprising a tubular body having an exterior surface extending between a proximal end and an opposing distal insertion end, the body also having an interior surface bounding a passageway extending between the proximal end and the distal insertion end, the passageway of the second dilator being configured to receive the tubular body of the first dilator (Fig. 5), the second dilator mechanically engaging with the first mating member such that the second dilator is forced to travel along a fixed path (Fig. 5) that prevents free rotation of the second dilator relative to the first dilator while at least a portion of the second dilator is being advanced over the first dilator.

Claims 2, 5, 19, 20, 21: Polleau teaches a second mating member comprises a mating member/tang (2') formed on the interior surface of the second dilator, the second mating member being configured to engage (3') with the first mating member (3") when the first dilator is received within the linear passageway of the second dilator (Fig. 5).

Claims 8, 16, 25: Polleau teaches a third mating member formed on the exterior surface of the second dilator.

Claim 37: Polleau teaches a portion of the second mating member (3', a portion in the longitudinal middle) is spaced apart from the distal insertion end of the tubular body (Fig. 2).

Claim 38: Polleau teaches the first mating member is formed at the distal end of the tubular body (3" extends to the distal end of the body).

Claims 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Simonson (U.S. Patent No. 7,008,431).

Simonson teaches a method for dilating bodily tissue, the method comprising: dilating bodily tissue with a distal insertion end of a first dilator (inner 12, Fig. 3); positioning a proximal end of the first dilator within a passageway of a tubular second dilator (second 12, Fig. 3); mechanically engaging (direct contact, snug fit) the second dilator with a first mating member (outer surface of tube 12) at the distal insertion end of the first dilator so as to prevent free rotation (shape of device prevents free rotation) of the second dilator around the first dilator through at least a portion of the advancement; and dilating bodily tissue with a distal insertion end of the second dilator (Fig. 3). Simonson teaches a third dilator over the second dilator (Fig. 3) and the first dilator.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by
Roehm, III et al. (U.S. Pub. No. 2004/0059339).

Claim 26: Roehm teaches a dilation system for dilating bodily tissue, the dilation system comprising: an elongate first dilator (26, Fig. 22B) comprising a first tubular body having an exterior surface extending between a proximal end and an opposing distal insertion end, a first tissue engaging member (24B) formed on and outwardly projecting from the exterior surface of the first tubular body at or toward the distal insertion end; and an elongate second dilator (27) comprising a second tubular body having an interior surface and an exterior surface each extending between a proximal end and an opposing distal insertion end, the interior surface bounding a passageway configured to receive the first tubular body (Fig. 2C), a second tissue engaging member (distal end of 27) being formed on the exterior surface of the second tubular body at or toward the distal insertion end.

Claim 27: Roehm teaches the second tissue engaging member comprises at least one thread (distal end of 27), thread portion, or tang (distal end of 27) outwardly projecting from the exterior surface of the second tubular body

Claim 28: Roehm teaches an elongate third dilator (31) comprising a third tubular body having an interior surface and an exterior surface each extending between a proximal end and an opposing distal insertion end, the interior surface bounding a passageway configured to receive the second tubular body, a third

tissue engaging member (distal end of 31, Fig. 2E) being formed on the exterior surface of the third tubular body at or toward the distal insertion end

Claim 29: Roehm teaches the first dilator (26) has a length and the second dilator (27) has a length that is shorter than the length of the first dilator (Fig. 2C)

Claim 30: Roehm teaches the distal insertion end of the first dilator and the second dilator terminate at a distal terminus (distal end Fig. 2C) and the proximal end of the first dilator and the second dilator terminate at a proximal terminus (27A), the first dilator having an marking on the exterior surface thereof such that when the proximal end of the second dilator is aligned with the marking, the distal terminus of the second dilator is aligned with the distal terminus of the first dilator (see 24A and 27A, Fig. 2C).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3,4,12 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Polleau (U.S. Patent No. 2,476,216) as applied to claims 1, 11,31 above and further in view of Bondioli (U.S. Patent No. 5,718,266).

Polleau teaches the claimed invention including mating members/tangs (3" and 3') but does not teach the first mating member having an outward projecting member.

However Bondioli teaches a projection extending outwardly from the center of the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bondioli, to modify the first mating member of Polleau, so that it has an outward projecting member, as this aides in preventing free rotation.

Claims 7,9,14,17, and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Polleau (U.S. Patent No. 2,476,216) as applied to claims 1, 11 and 26 above and further in view of Simonson (U.S. Patent No. 7,008,431).

Polleau teaches the claimed invention but does not specify tapered ends or the length of the tubes, however Simonson teaches tapered ends (Fig. 2) and each additional outer tube decreasing in length (Fig. 2) and a guidewire (16). It would have been obvious to one of ordinary skill in the art to combine the guidewire, the tapered ends and tubular lengths of Simonson with the telescopic tubes of Polleau as this would aid in an easier transition into the body.

Polleau teaches the claimed invention but is silent regarding a marking on the exterior surface of the dilator to see when the dilators are aligned, however Simonson teaches a marking (24) to indicate when the tube is in place. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a marking in the device of Polleau in order to indicate correct placement in the body.

Claims 13 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polleau (U.S. Patent No. 2,476,216) as applied to claims 11 and 19 above and further in view of Fisher (U.S. Patent No. 5,006,113).

Polleau teaches the claimed invention including the orientation and placement of the first and second mating members as described above, but does not teach threads as mating members, however Fisher teaches mating members that are threads (31 and 15, Fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use threads to connect two tubular structures as this keeps the two structures together.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polleau (U.S. Patent No. 2,476,216) as applied to claim 31 above.

Polleau teaches the claimed invention but is silent regarding radiolucent material being used, however it would have been obvious to one of ordinary skill in the art to incorporate radiolucent material into the tubes as this would aid in viewing placement of the device using imaging tools. Moreover, it has been held to be within the general skill of worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Allowable Subject Matter

Claims 6, 24, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 15 has a drawing objection as stated above, and the examiner recommends changing the language of claim 15 to be analogous to the limitations of claim 6 in order to put the claim in condition for allowance; and upon correction of the drawing objection, claim 15 would be objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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